Patent Law Update: Association for Molecular Pathology v. USPTO

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Federal Circuit Hears Arguments in *Association for Molecular Pathology v. USPTO*

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On April 4, 2011, before a well-filled courtroom, the Court of Appeals for the Federal Circuit heard arguments in the *Myriad* case.[1] The case could potentially reach the issue of subject matter patentability of claims to isolated DNA under Section 101 of the patent statute.

Before reaching the merits of the arguments, however, there was an in-depth inquiry into the critical procedural question: did the district court have jurisdiction to hear the case? In particular, did the plaintiffs demonstrate that they had standing to sue?

The Association for Molecular Pathology (AMP) urged that several individuals and groups had demonstrated sufficient likelihood of injury to confer standing. The panel appeared skeptical, however, that there was enough evidence of particularized harm for any one of the plaintiffs. The panel also expressed concern that if they found standing on the facts before them in this case, a whole new category of litigants would be created to challenge existing patents.

Turning to the merits, the panel appeared skeptical of the arguments of both the U.S. government as represented by the Department of Justice, and of the large group of plaintiffs, which Judge Lourie referred to as a large "et al." The panel's questioning indicated that the theories of the plaintiffs and government ran contrary to established case law on chemical entities in general, as well as contrary to longstanding U.S. Patent and Trademark Office policy on nucleic acids.

The judges struggled to identify a way to differentiate between genomic DNA and isolated DNA, spending several minutes debating with counsel whether there was a difference between mining a metal stuck in a rock, then processing it to obtain the pure metal *versus* isolating the DNA from a cell and purifying a gene from a genome. The Department of Justice urged using a "magical microscope" as a helpful analytic tool. If such a microscope could see into the human body and determine that the claimed invention was present, then it would be a product of nature and not patent-eligible. AMP posited a pair of tweezers to be invented in the future that could pluck genes out of a genome. The judges maintained their focus on whether chemical bonds are formed or broken as the touchstone for whether a product is a product of nature or a product of human intervention. Judge Lourie commented, "This isn't just research by tweezers."

Overall, the judges appeared concerned about creating a sweeping change that would undermine the settled expectations of the biotech industry. Such a sweeping change as was urged by AMP and the U.S., Judge Moore suggested, should be the province of the Congress, and not of either the judiciary or the executive branch.

An opinion is expected by late summer 2011.

[1] *Ass'n for Molecular Pathology et al*, v. *U.S. P.T.O* and Myriad Genetics, Inc. and Betz et al. (No. 2010-1406)

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